U.S. FOOD & DRUG ADMINISTRATION

12/11/2018

Claire Tighe
MuckRock News DEPT MR 63573
411A Highland Ave
Somerville, MA 02144

Dear Claire Tighe,

The attached record(s) are being provided by the Office of Regulatory Affairs (ORA) Division of Information Disclosure Policy – Philadelphia in response to your request **2018-9519, 9533** for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

BAYER INSPECTION RECORDS

Your request is granted in part.

After a thorough review of the responsive records, we have determined that portions of the documents are exempt from disclosure under FOIA exemptions (b)(4), (b)(6)of the FOIA 5 U.S.C. § 552, as amended and delineated below:

- Exemption (b)(4) permits the withholding of "trade secrets" (TS) and "commercial confidential information" (CCI). Disclosure of this information would impair the government's ability to obtain necessary information in the future and cause substantial harm to the competitive position of the person from whom the information was obtained. Under the balancing test of this exemption, we are withholding all proprietary information identified as TS and CCI

- Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth, under exemption (b)(6), to release the personal identifying information of certain third parties.

Philadelphia considers your request closed. If you have any questions about this response, you may contact Michele Y. Beckett at 215-717-3073. Please be advised that your request may have been submitted to one or more component offices within FDA [DAL-DO, NWJ-DO]. These offices will reply to

you directly. This not the agency final response and you will receive additional appeal rights with the final response, so you do not have to act at this time.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to:

Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
e-mail FOIARequest@PSC.hhs.gov.

Please clearly mark both the envelope and your letter or e-mail "**FDA** Freedom of Information Act Appeal.

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact **person that worked on request**. You may also contact the FDA Public Liaison for assistance at

Office of the Executive Secretariat
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is as follows:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road–OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

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ADMINISTRATION

Please do not submit payment until you receive an invoice. The following charges for this request to date may be included in a monthly invoice:

Reproduction=$0.00 Search=$34.50 Review $92.00 Other $1.00 Total= $127.50

Sincerely

Michele Y. Beckett

Michele Y. Beckett
Government Information Specialist

U.S. Food and Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD 20857
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